NowCheck

Total Solution for COVID-19 Diagnosis

- NowCheck COVID-19 Ag Test
  - Nasopharyngeal swab version
  - Nasal swab version
- NowCheck COVID-19 IgM/IgG Test

BIONOTE

NowCheck COVID-19 Ag Test

The NowCheck COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx or nasal cavity.

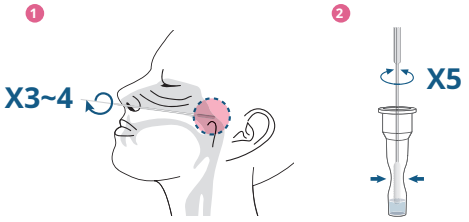
Specifications

- Specimen : Nasopharyngeal swab, Nasal swab
- Testing time : 15~30 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2~30°C (36~86°F)

Test Procedure

Nasopharyngeal swab

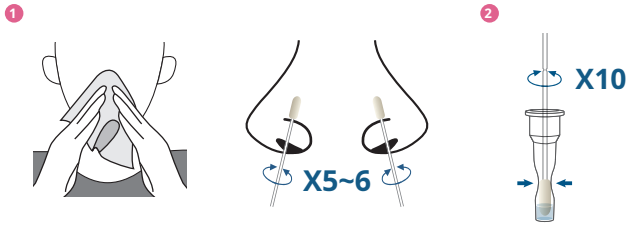
1. Insert a nasopharyngeal swab into the nostril of the patient, and rotate the swab over the posterior nasopharynx surface 3~4 times.
2. Insert the swab into an extraction buffer tube, and stir it more than 5 times while squeezing the tube.



or

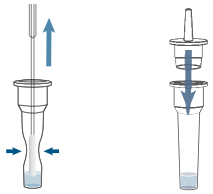
Nasal swab

1. After getting a patient to blow one's nose, insert a nasal swab into one of the nostrils, and rotate the swab against the nasal wall 5-6 times. Repeat in the other nostril, using the same swab.
2. Insert the swab into an extraction buffer tube, and stir it more than 10 times while squeezing the tube.



Analysis

3. Remove the swab while squeezing the sides of the tube, and press the nozzle cap tightly onto the tube.

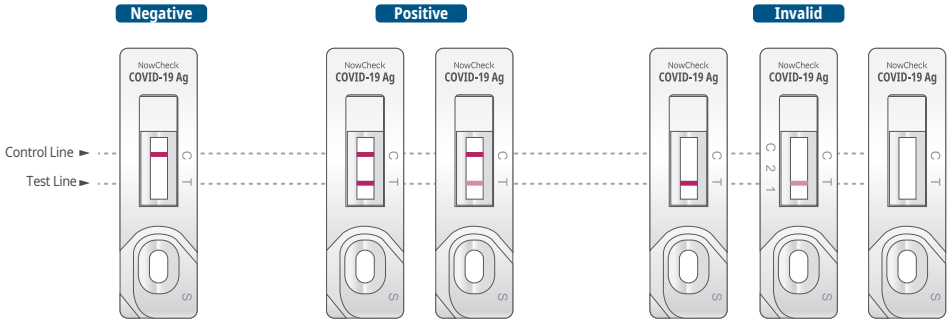


4. Apply 3 drops of the extracted specimen to the specimen hole of the test device.

5. Read the test result after 15~30 min. The test can be read up to 30 min.

** Do not read test results after 30 min.
It may give false results.

Test Result

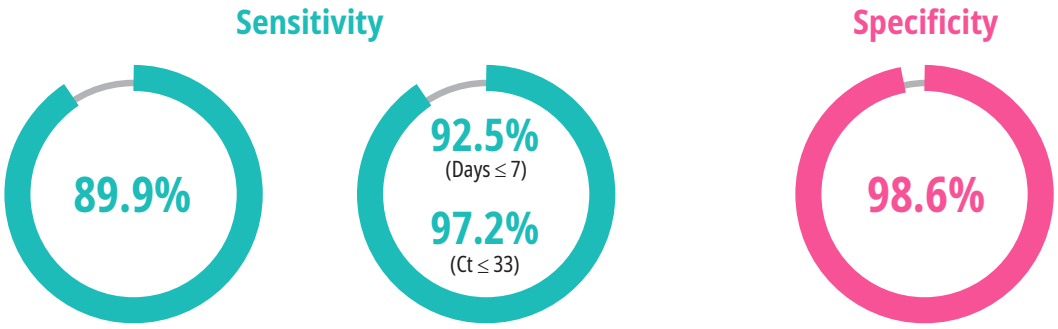


NowCheck COVID-19 Ag Test

Clinical Performance

:: Evaluation study in Brazil (January – February 2021, FIND)

- A total of 218 nasal & nasopharyngeal swab specimens from symptomatic patients were tested.



Specimens from symptomatic patients (N=218)		RT-PCR (Nasopharyngeal)		
		Positive	Negative	Total
NowCheck COVID-19 Ag (Nasal, Nasopharyngeal)	Positive	71	2	73
	Negative	8	137	145
	Total	79	139	218

	NowCheck COVID-19 Ag (Nasopharyngeal / Nasal)
Clinical Sensitivity (95% CI)	89.9% (81.3, 94.8)
Sensitivity days ≤7	92.5% (83.7, 96.8)
Sensitivity Ct ≤ 33	97.2% (90.4, 99.2)
Sensitivity Ct ≤ 25	100% (92.3, 100)
Clinical Specificity (95% CI)	98.6% (94.9, 99.6)

:: Evaluation study in Brazil (July – August 2020, FIND)

- A total of 400 nasopharyngeal swab specimens from symptomatic patients were tested.

Specimens from symptomatic patients (N=400)		RT-PCR (Nasopharyngeal)		
		Positive	Negative	Total
NowCheck COVID-19 Ag (Nasopharyngeal)	Positive	91	8	99
	Negative	11	290	301
	Total	102	298	400

	NowCheck COVID-19 Ag (Nasopharyngeal)
Clinical Sensitivity (95% CI)	89.2% (81.7, 93.9)
Sensitivity days ≤7	92.2% (84.8, 96.2)
Sensitivity Ct ≤ 33	91.4% (83.9, 95.6)
Sensitivity Ct ≤ 25	94.8% (85.9, 98.2)
Clinical Specificity (95% CI)	97.3% (94.8, 98.6)

NowCheck COVID-19 Ag Test

SARS-CoV-2 Variant Study

:: Internal evaluation study (July 2021, BIONOTE Inc. Laboratory)

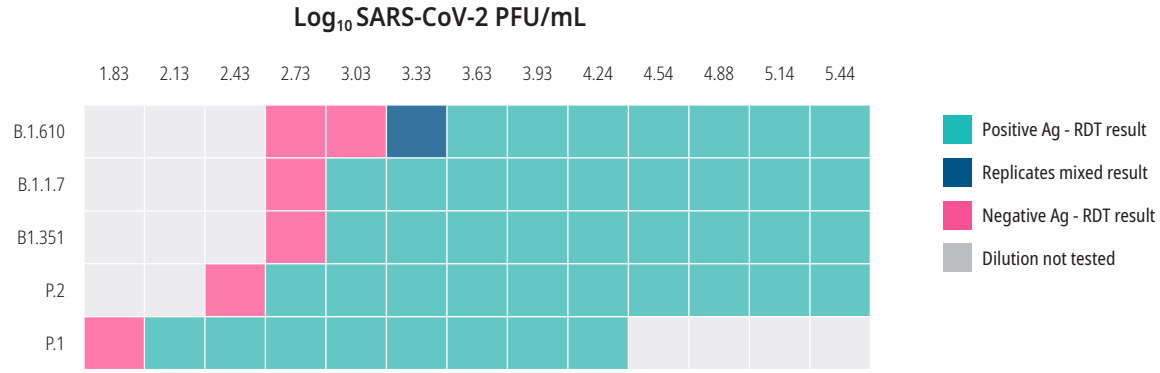
- *In-silico* analysis of nucleocapsid (N) protein
- Analytical sensitivity tests using recombinant N protein
- Analytical sensitivity tests using cultured virus

Variants		First identified country	*In-silico* analysis	Analytical sensitivity test	
Name	Lineage			Recombinant protein	Cultured virus
Wuhan-Hu-1	B	China		Confirmed	Confirmed
Alpha	B.1.1.7	United Kingdom	Confirmed	Confirmed	Confirmed
Beta	B.1.351	South Africa	Confirmed	Confirmed	Confirmed
Gamma	P.1	Brazil	Confirmed	Confirmed	To be tested
Kappa	B.1.617.1	India	Confirmed	Confirmed	To be tested
Delta	B.1.617.2	India	Confirmed	Confirmed	To be tested

:: Evaluation study in Switzerland (June 2021, University of Geneva & FIND)

- Analytical sensitivity tests using cultured virus
- NowCheck COVID-19 Ag Test showed
  - Better (2~16 times) performance on all variants than on the early pandemic lineage
  - Best performance on the Gamma variant among the 9 commercial kits evaluated together

Variants	Early pandemic lineage (B.1.160)	Alpha (B.1.1.7)	Beta (B.1.351)	Zeta (P.2)	Gamma (P.1)
Analytical sensitivity (PFU/mL)	$10^{3.33}$/ Control	$10^{3.03}$ / 2 times	$10^{3.03}$ / 2 times	$10^{2.73}$ / 4 times	$10^{2.13}$ / 16 times



NowCheck COVID-19 Ag Test provides reliable and highly accurate results for detecting the abovementioned SARS-CoV-2 variants.

NowCheck COVID-19 Ag Test

Analytical Performance

:: Limit of Detection (LoD)

SARS-CoV-2 strain tested	Virus stock titer	Specimen type	LoD (Spiking titer)	Final working titer
NCCP 43326/ 2020 /Korea	1 X $10^{6.2}$ $TCID_{50}$/ml	Direct nasopharyngeal swab	3.12 X $10^{2.2}$ $TCID_{50}$/ml	6.24 X $10^{1.2}$ $TCID_{50}$/ml
		Direct nasal swab	1.56 X $10^{2.2}$ $TCID_{50}$/ml	5.37 X $10^{1.2}$ $TCID_{50}$/ml

:: No Cross-reactivity

No cross-reactivity with potential cross-reactive substances except SARS-CoV

Category	Sort	Result
Virus	SARS-coronavirus	POS
	MERS-coronavirus	NEG
	Human Coronavirus	NEG
	Influenza A	NEG
	Influenza B	NEG
	Respiratory syncytial virus	NEG
	Human Metapneumovirus (hMPV)	NEG
	Parainfluenza virus	NEG
	Rhinovirus	NEG
	Enterovirus	NEG
	Adenovirus	NEG
	Human immunodeficiency virus lysate	NEG

Category	Sort	Result
Bacteria	Haemophilus influenzae	NEG
	Mycoplasma pneumoniae	NEG
	Streptococcus pneumonia	NEG
	Streptococcus pyrogens	NEG
	Streptococcus salivarius	NEG
	Candida albicans	NEG
	Bordetella pertussis	NEG
	Moraxella catarrhalis	NEG
	Pseudomonas aeruginosa	NEG
	Staphylococcus epidermidis	NEG
	Mycobacterium tuberculosis	NEG
Others	Pooled human nasal wash – representative of normal respiratory microbial flora	NEG

:: No Cross-reactivity & Interference

- No interference with endogenous/exogenous interfering substances

:: Inactivation by the extraction buffer

- SARS-CoV-2 was inactivated by the extraction buffer in 2 minutes.

Type	Virus Spiking	Cytopathic Effect	Interpretation
Extraction buffer	O	No CPE	Virus inactivated
Cell culture media		CPE	Positive control

:: Matrix Equivalency

- Clinical matrix including swabs and VTM do not affect the detection of COVID-19 Ag.

NowCheck COVID-19 IgM/IgG Test

NowCheck COVID-19 IgM/IgG Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma, or whole blood.

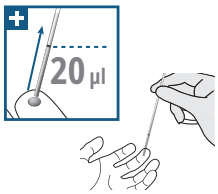
Specifications

- Specimen : Whole blood, Serum, Plasma
- Testing time : 10~15 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2~30°C (36~86°F)

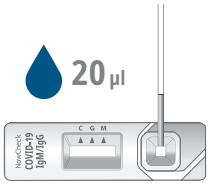
Test Procedure

[Using Capillary whole blood]

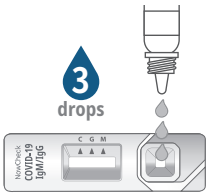
1. Collect the 20 µl of capillary whole blood to the black line



2. Add the collected blood to the specimen hole



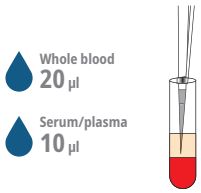
3. Add 3 drops (90 µl) of buffer vertically



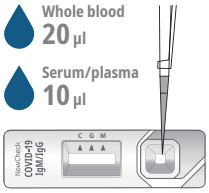
4. Read the test result in 10~15 min.

[Using serum/plasma/whole blood]

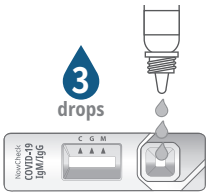
1. Collect the serum, plasma (10 µl) or whole blood (20 µl) with a micropipette



2. Add the collected blood to the specimen hole

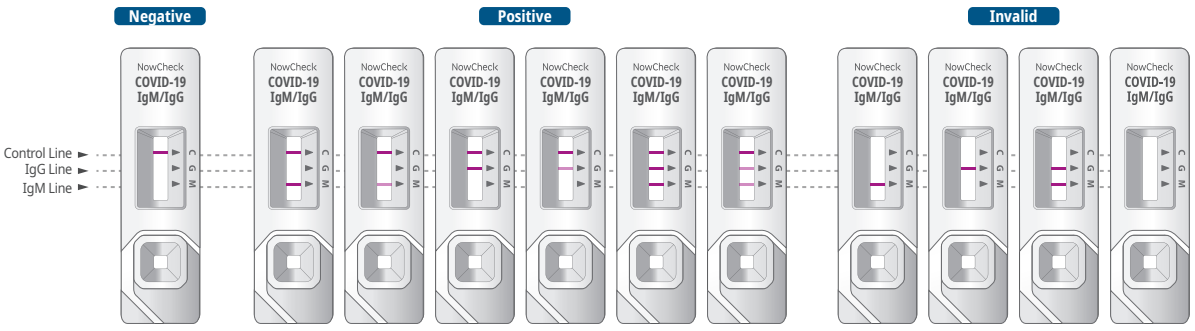


3. Add 3 drops (90 µl) of buffer vertically



4. Read the test result in 10~15 min.

Test Result



NowCheck COVID-19 IgM/IgG Test

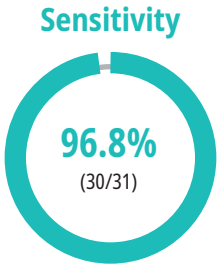
Performance

:: Clinical evaluation

A total of 105 serum specimens from patients confirmed by Real-time PCR were analyzed.
The results are as shown below:

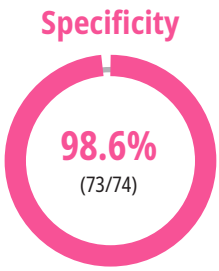
- Diagnostic Sensitivity

Positive specimens (N=31)		NowCheck COVID-19 IgM/IgG Test			
		IgM(+)	IgG(+)	IgM(+) and/or IgG(+)	
Days (post-symptom onset)	0 - 7	100% (1/1)	100% (1/1)	100% (1/1)	96.8% (30/31)
	8 - 14	66.7% (2/3)	100% (3/3)	100% (3/3)	
	≥ 15	88.9% (24/27)	96.3% (26/27)	96.3% (26/27)	



- Diagnostic Specificity

Negative specimens (N=74)	NowCheck COVID-19 IgM/IgG Test		
	IgM(-)	IgG(-)	IgM(-) and IgG(-)
Confirmed by Real time-PCR	98.6% (73/74)	100% (74/74)	98.6% (73/74)



The NowCheck COVID-19 IgM/IgG Test showed 96.8% of sensitivity and 98.6% of specificity, compared to the Real-time PCR method.

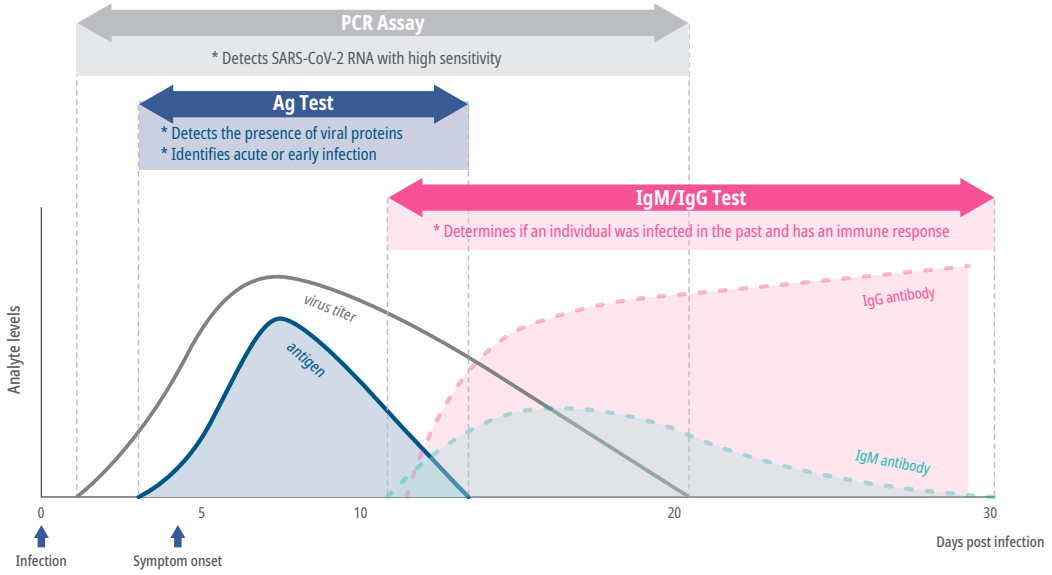
* Conducted in July 2020 at Department of Laboratory medicine, Seoul National University Bundang Hospital
** Reference: PowerChek™ 2019-nCoV Real-time PCR kit (KCDC approved, FDA EUA)

:: Limit of Detection (LoD)

The LoD of NowCheck COVID-19 IgM/IgG Test for SN titer was 1:40.

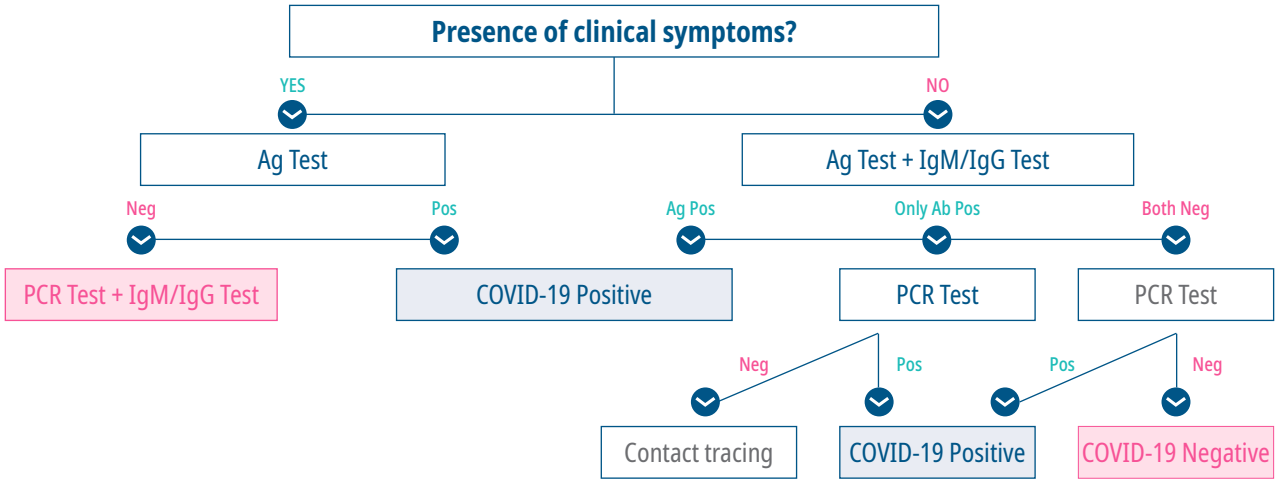
Total Solution for COVID-19 Diagnosis

Why Do We Need Antigen and Antibody Tests?



Diagnostic Algorithm

For individuals suspected to have COVID-19



Ordering Information

Product No.	Product Name	Product Type	Packing Unit
RG1901DG (Nasopharyngeal) RG1901DGN (Nasal)	NowCheck COVID-19 Ag Test	Device	25 Tests/Kit
RB2901DG	NowCheck COVID-19 IgM/IgG Test	Device	25 Tests/Kit
RG1901CD	NowCheck COVID-19 Ag Control	Control	10 Tests/Kit
RB2901CD	NowCheck COVID-19 IgM/IgG Control	Control	10 Tests/Kit

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